560-2421

Producers of Quality Nonprescription Medicines and Dietary Supplements for Self-Care

CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

Formerly Nonprescription Drug Manufacturers Association

October 3, 2000

Charles J. Ganley, M.D.
Director, Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research
Food and Drug Administration
Rockville, Maryland 20857

Dear. Dr. Ganley:

We are writing on behalf of the Label Coordinators Group of the Consumer Healthcare Products Association (CHPA) to request a meeting with FDA to discuss the need for class exemptions for OTC drug convenience sizes in selected OTC categories, in the context of the final rule on OTC label content and format.

Based on our April 17 meeting with Dr. Woodcock, we understand that approaches to convenience sizes, which represent less than 1% of the OTC drug retail marketplace, might include pared labeling in which certain selected label information is available on the outer container, while full labeling is available in proximity to the convenience package (e.g., tear-off leaflets) and/or within that package. Examples of such label configurations have been used for many years on the OTC drug retail shelf (e.g, analgesic tins with package inserts).

In order to further the discussion on this matter for the meeting, we provide additional information in this letter, which addresses a recent letter from FDA to counsel for one of our members (Ganley letter to Dormer dated August 28, 2000, Docket No. 98N-0337) denying an exemption request; and offers specific recommendations for a monograph-by-monograph amendment approach that would permit class exemptions for convenience sizes in selected OTC drug categories of products.

I. FDA's Authority to Provide Requested Relief for Convenience Size OTC Drug Product Packages

FDA has ample authority to provide the requested relief for convenience size OTC drug products. Section 201 (k) of the FDC Act, 21 USC § 321 (k), which provides that all required label information must also appear on the outside retail package, is not an inflexible requirement. For example, FDA has promulgated a regulation permitting off-package declaration of required

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information where the container is too small to accommodate certain required information. Section § 201.10 (i) of 21 CFR, which was promulgated in part pursuant to the statutory authority of Section 201 (k), provides that a drug container too small or otherwise unable to bear active ingredient information *shall be* exempt from that requirement, so long as certain standards are met.

First, the label must bear the proprietary name and established name (if any) of the drug, the lot or control number, and the name of the manufacturer, packer or distributor. Second, all other required information must appear on the carton or other outer container "*if* such ... *outer container*, or wrapper has sufficient space to bear such information *or such complete label information appears on a leaflet with the package*." [Emphases added.] Thus, in the case of convenience sizes of OTCs held in a shelf container, FDA could deem the shelf container to be the "outer container" referred to in § 201.10(i)(2) on which the required information is placed.[1] Alternatively, a "leaflet with the package" could be used, which could be a tablet of leaflets affixed to the shelf container in which the OTC convenience size products are displayed at

[1] In the August 28, 2000 letter to Mr. Dormer, responding to a request by Block Drug for a small size exemption from the OTC label rule, Dr. Ganley, on behalf of FDA, maintained that the OTC product shelf container with full required OTC drug labeling would not be suitable presentation of Drug Facts information for an envelope package with an extra fold-down panel, all of which is over-wrapped with cellophane or other transparent material. Dr. Ganley hypothesized a series of unsubstantiated speculations: that consumers would not be able to see the shelf container in gasmarts at nighttime, that the type size would not be large enough for consumers to read on a shelf container unless they could it pick up, or, finally, that retailers might not retain the shelf container at all because there is no legal requirement for them to do so. In fact, the FDC Act provides that a drug is misbranded if required information is not provided in a manner such that it is likely to be read under customary conditions of purchase. 21 USC § 352 (c). A retailer could be charged with misbranding a drug if he discards the shelf container bearing required labeling or otherwise makes the labeling unavailable for the purchaser to see. FDA's speculation that retailers will not abide by the law could, arguably, be raised as an objection to any small package held in a shelf container, thus rendering the small package regulation a nullity. If FDA believes that the small package regulation should be amended or repealed, it must do so through notice and comment rulemaking pursuant to the Administrative Procedure Act. It cannot do so by means of a letter dismissing out of hand the use of labeled shelf containers with the package.

With respect to Dr. Ganley's concern that type sizes for the Drug Facts labeling on the shelf container will not be sufficient for consumers to read, Dr. Ganley stated that he assumes that consumers hold a product in their hand a "short distance" from their eyes. The short distance is not specified, however. Normal reading distance is considered 40 cm., or about 16 inches, the distance at which most eye charts are read. While consumers may often pick up a product to read the labeling (which is normally on the back of the package), they nevertheless should be able to read labeling on the shelf tray, as it is easy to stand 16 inches from the shelf.

With respect to the FDA's stated fear that retailers will not retain the tray, especially when only a few packages remain in it for sale, apart from the legal requirement described above, a shelf tray is needed as a practical necessity to hold the packages even when there are only a few packages left in the shelf container to maintain order on the shelf. Further, most shelf trays allow a few extra packages to be added by the retailer as a part of retail shelf maintenance when discarding a used shelf tray that is near empty.

retail.[2] Leaflets with a package are permitted under the small package regulation, and there is no question that their use is permissible for convenience sizes.[3]

FDA regulations have long permitted use of leaflets for cosmetic ingredient labeling, which is required to avoid allergic reactions as well as to facilitate value comparisons.[4] The FDA regulations permit use of a shelf display with leaflets that bear cosmetic ingredient labeling as an alternative to placement of the declaration on the outer package. 21 CFR § 701.3 (i)-(k). When a shelf display with leaflets is used, FDA specifies that steps must be taken to assure, for example, that the display is designed and located so the labeling is easily accessible to the purchaser under customary conditions of retail sale, that sufficient copies of the consumer leaflet are included with the cosmetic shipment, and that the display unit to which the leaflets are affixed bears the words "Federal law requires ingredient lists to be displayed here." FDA could develop a guidance document for use of leaflet-bearing displays for OTC convenience sizes, which would parallel the regulatory requirements FDA has established for cosmetic displays.

II. Selected Monograph-based Class Specific Exemptions for OTC Drug Products Marketed as Convenience Sizes

CHPA has reviewed the marketing practices of its members in terms of which OTC drug categories are typically marketed using convenience size packaging. We have considered the various package configurations for convenience sizes. We have also considered how a label format and content exemption for convenience sizes might be applied to the monograph categories of interest. The following is a list of enclosed suggested monograph exemptions by category and formulation, which can serve as a basis for discussion at our requested meeting.

- Antacids - liquids
- Antacids - solids
- Analgesic - liquids
- Analgesic - solids
- Cough/Cold - liquids
- Cough/Cold - solid oral
- Gastrointestinal - liquids

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[2]Dr. Ganley's letter did not address leaflets, as Block had not requested permission to use them in its original petition.

[3] We acknowledge that by its terms 21 CFR § 201.10 (i) applies specifically to packages too small to accommodate information required by section 502(e)(1)(A)(ii), i.e., the name and quantity of each active ingredient. (The regulation has not been amended to conform to FDAMA, which required a drug label also to bear the name of each inactive ingredient and the quantity of each active ingredient.) However, the regulation provides support for the proposition that FDA may permit the use of shelf container labeling or leaflets with the package for convenience size products too small to accommodate required information, irrespective of what the required information may be.

[4] 38 Fed. Reg. at 3524 (February 7, 1973) (Cosmetic Ingredient Labeling; Notice of Proposed Rulemaking).

- Gastrointestinal - solids
- Laxative - liquids
- Laxative - solids
- Topical Products *(Note: Separate monograph amendment suggestions have been created for each of the following topical subcategories:*
  - *Anorectal*
  - *Antifungal*
  - *External Analgesics*
  - *Ophthalmics*
  - *Oral Discomfort Products*
  - *Topical Antitussives)*
- Antitussive lozenges
- Oral Anesthetic lozenges
- Oral Demulcent lozenges

In closing we look forward to the opportunity to meet with the agency on this matter.

Sincerely yours,

R. William Soller, Ph.D.
Senior Vice President and
Director of Science & Technology

Eve E. Bachrach
Senior Vice President,
General Counsel and Secretary

Enc: As stated.

cc. Janet Woodcock, M.D.
Murray M. Lumpkin, M.D.
Robert Delap, M.D.
Erica L. Keys

WS/jq:Labeling/Convenience Sizes/GanleyLetConvSize

Consumer Healthcare Products Association

Draft Proposed Convenience-Size Exemption for Antacid Products (liquid dosage forms)

To be inserted in the Monograph:

For products packaged for easy portability and for which the printable space is insufficient to accommodate all required labeling in the required format or are single-use non-reclosable packages or contain no more than 4 fluid ounces, the following shall apply:

(1) The 60 percent requirement stated in Sec. 201.66(d)(10) will be waived as a requirement for using the modifications given in Sec. 201.66(d)(10)(i) through Sec. 201.66(d)(10)(v).

(2) The labeling shall meet the requirements of Sec. 201.66(c) of this chapter except that
  (a) the horizontal barlines and hairlines described in Sec. 201.66(d)(8), may be omitted,.
  (b) the title, "Drug Facts" described in Sec 201.66(d)(1)and (2) is to be retained at a type size of 7.1-point, per the modified format;
  (c) headings, and information described in Sec. 201.66(c)(1), (c)(3), and (c)(7) may be omitted,
  (d) a paragraph format may be used,
  (e) the headings, subheadings, and information described in Sec. 201.66(c)(2), (c)(4), (c)(5), and (c)(6) may be presented as follows:
    (i) The active ingredients (Sec. 201.66(c)(2) of this chapter) shall be listed in alphabetical order, except the heading, "Active(s)," may be used..
    (ii) The heading and the indication required by Sec. 201.66(c)(4) may be limited to: "Use (in bold type) for sour stomach or acid indigestion."
    (iii) Warnings visible at the point of purchase may be limited to specialty warnings and those under the "Do not use" heading, provided that a prominent and conspicuous instruction "See inside for full Drug Facts" (or another appropriate instruction) appears on the package, and all required warnings are available when the package is opened.
    (iv) Directions may be omitted from the outside of the package, provided that a prominent and conspicuous instruction "See inside for full Drug Facts " and all required dosage instructions are available when the package is opened.
    (v) Inactive ingredients may be omitted from the outside of the package, provided a prominent and conspicuous instruction "See inside for full Drug Facts" and inactive ingredients are available when the package is opened.
    (vi) "Other information" and "Questions" may appear outside the Drug Facts box, or inside when the package is opened, except that products containing aspartame as an inactive ingredient shall bear a statement on the outer container to the following effect: Phenylketonurics: Contains Phenylalanine (__)mg Per (Dosage Unit).
    (vii) If columns are used, the title "Drug Facts (continued)," may be omitted, provided a visual graphic (e.g., an arrow) is used to signal the continuation of the Drug Facts labeling to the next adjacent column.

(3) Alternatively, in instances where packaging constraints, such as configuration and tamper-evident features, do not permit all information to be visible on the outer package or a package insert may not be included within the package, the Drug Facts box and other information may be provided on secondary packaging, provided that the full Drug Facts labeling is provided in the form of a tear-off pad, is printed on the shelf tray used to display the product, and complies with all formatting requirements of the rule.

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Consumer Healthcare Products Association

Draft Proposed Convenience-Size Exemption for Antacid Products (solid dosage forms)

To be inserted in the Monograph:

For products packaged for easy portability and for which the printable space is insufficient to accommodate all required labeling in the required format or are single-use non-reclosable packages, or contain no more than 12 dosage units, the following shall apply:

(1) The 60 percent requirement stated in Sec. 201.66(d)(10) will be waived as a requirement for using the modifications given in Sec. 201.66(d)(10)(i) through Sec. 201.66(d)(10)(v).

(2) The labeling shall meet the requirements of Sec. 201.66(c) of this chapter except that
  (a) the horizontal barlines and hairlines described in Sec. 201.66(d)(8), may be omitted,.
  (b) the title, "Drug Facts" described in Sec 201.66(d)(1)and (2) is to be retained at a type size of 7.1-point, per the modified format;
  (c) headings, and information described in Sec. 201.66(c)(1), (c)(3), and (c)(7) may be omitted,
  (d) a paragraph format may be used,
  (e) the headings, subheadings, and information described in Sec. 201.66(c)(2), (c)(4), (c)(5), and (c)(6) may be presented as follows:
    (i) The active ingredients (Sec. 201.66(c)(2) of this chapter) shall be listed in alphabetical order, except the heading, "Active(s)," may be used..
    (ii) The heading and the indication required by Sec. 201.66(c)(4) may be limited to: "Use (in bold type) for sour stomach or acid indigestion."
    (iii) Warnings visible at the point of purchase may be limited to specialty warnings and those under the "Do not use" heading, provided that a prominent and conspicuous instruction "See inside for full Drug Facts" (or another appropriate instruction) appears on the package, and all required warnings are available when the package is opened.
    (iv) Directions may be omitted from the outside of the package, provided that a prominent and conspicuous instruction "See inside for full Drug Facts " and all required dosage instructions are available when the package is opened.
    (v) Inactive ingredients may be omitted from the outside of the package, provided a prominent and conspicuous instruction "See inside for full Drug Facts" and inactive ingredients are available when the package is opened.
    (vi) "Other information" and "Questions" may appear outside the Drug Facts box, or inside when the package is opened, except that products containing aspartame as an inactive ingredient shall bear a statement on the outer container to the following effect: Phenylketonurics: Contains Phenylalanine (__)mg Per (Dosage Unit).
    (vii) If columns are used, the title "Drug Facts (continued)," may be omitted, provided a visual graphic (e.g., an arrow) is used to signal the continuation of the Drug Facts labeling to the next adjacent column.

(3) Alternatively, in instances where packaging constraints, such as configuration and tamper-evident features, do not permit all information to be visible on the outer package or a package insert may not be included within the package, the Drug Facts box and other information may be provided on secondary packaging, provided that the full Drug Facts labeling is provided in the form of a tear-off pad, is printed on the shelf tray used to display the product, and complies with all formatting requirements of the rule.

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Consumer Healthcare Products Association

Draft Proposed Convenience-Size Exemption for
Liquid Dosage Forms
Internal Analgesics/Menstrual Products

To be inserted in the Monograph:

For products packaged for easy portability and for which the printable space is insufficient to accommodate all required labeling in the required format or are single-use non-reclosable packages, or contain no more than 4 fluid ounces, the following shall apply:

(1) The 60 percent requirement stated in Sec. 201.66(d)(10) will be waived as a requirement for using the modifications given in Sec. 201.66(d)(10)(i) through Sec. 201.66(d)(10)(v).

(2) The labeling shall meet the requirements of Sec. 201.66(c) of this chapter except that
  (a) the horizontal barlines and hairlines described in Sec. 201.66(d)(8), may be omitted,.
  (b) the title, "Drug Facts" described in Sec 201.66(d)(1)and (2) is to be retained at a type size of 7.1-point, per the modified format;
  (c) headings, and information described in Sec. 201.66(c)(1), (c)(3), and (c)(7) may be omitted,
  (d) a paragraph format may be used,
  (e) the headings, subheadings, and information described in Sec. 201.66(c)(2), (c)(4), (c)(5), and (c)(6) may be presented as follows:
    (i) The active ingredients (Sec. 201.66(c)(2) of this chapter) shall be listed in alphabetical order, except the heading, "Active(s)," may be used.
    (ii) The heading and the indication required by Sec. 201.66(c)(4) may be limited to: "Use (in bold type) for temporary pain of (insert "headache" or "muscular aches" or menstrual discomfort" or "toothache" or any combination of the above.
    (iii) Warnings visible at the point of purchase may be limited to specialty warnings and those under the "Do not use" heading, provided that a prominent and conspicuous instruction "See inside for full Drug Facts" (or another appropriate instruction) appears on the package, and all required warnings are available when the package is opened.
    (iv) Directions may be omitted from the outside of the package, provided that a prominent and conspicuous instruction "See inside for full Drug Facts " and all required dosage instructions are available when the package is opened.
    (v) Inactive ingredients may be omitted from the outside of the package, provided a prominent and conspicuous instruction "See inside for full Drug Facts" and inactive ingredients are available when the package is opened.
    (vi) "Other information" and "Questions" may appear outside the Drug Facts box, or inside when the package is opened, except that products containing aspartame as an inactive ingredient shall bear a statement on the outer container to the following effect: Phenylketonurics: Contains Phenylalanine (__)mg Per (Dosage Unit).
    (vii) If columns are used, the title "Drug Facts (continued)," may be omitted, provided a visual graphic (e.g., an arrow) is used to signal the continuation of the Drug Facts labeling to the next adjacent column.

(3) Alternatively, in instances where packaging constraints, such as configuration and tamper-evident features, do not permit all information to be visible on the outer package or a package insert may not be included within the package, the Drug Facts box and other information may be provided on secondary packaging, provided that the full Drug Facts labeling is provided in the form of a tear-off pad, is printed on the shelf tray used to display the product, and complies with all formatting requirements of the rule.

WS/WB/b 8/30/00

Consumer Healthcare Products Association

Draft Proposed Convenience-Size Exemption for
Solid Dosage Forms
Internal Analgesics

To be inserted in the Monograph:

For products packaged for easy portability and for which the printable space is insufficient to accommodate all required labeling in the required format or are single-use non-reclosable packages, or contain no more than 12 dosage units, the following shall apply:

(1) The 60 percent requirement stated in Sec. 201.66(d)(10) will be waived as a requirement for using the modifications given in Sec. 201.66(d)(10)(i) through Sec. 201.66(d)(10)(v).

(2) The labeling shall meet the requirements of Sec. 201.66(c) of this chapter except that
  (a) the horizontal barlines and hairlines described in Sec. 201.66(d)(8), may be omitted,.
  (b) the title, "Drug Facts" described in Sec 201.66(d)(1)and (2) is to be retained at a type size of 7.1-point, per the modified format;
  (c) headings, and information described in Sec. 201.66(c)(1), (c)(3), and (c)(7) may be omitted,
  (d) a paragraph format may be used,
  (e) the headings, subheadings, and information described in Sec. 201.66(c)(2), (c)(4), (c)(5), and (c)(6) may be presented as follows:
    (i) The active ingredients (Sec. 201.66(c)(2) of this chapter) shall be listed in alphabetical order, except the heading, "Active(s)," may be used.
    (ii) The heading and the indication required by Sec. 201.66(c)(4) may be limited to: "Use (in bold type) for temporary pain of (insert "headache" or "muscular aches" or menstrual discomfort" or "toothache" or any combination of the above.
    (iii) Warnings visible at the point of purchase may be limited to specialty warnings and those under the "Do not use" heading, provided that a prominent and conspicuous instruction "See inside for full Drug Facts" (or another appropriate instruction) appears on the package, and all required warnings are available when the package is opened.
    (iv) Directions may be omitted from the outside of the package, provided that a prominent and conspicuous instruction "See inside for full Drug Facts " and all required dosage instructions are available when the package is opened.
    (v) Inactive ingredients may be omitted from the outside of the package, provided a prominent and conspicuous instruction "See inside for full Drug Facts" and inactive ingredients are available when the package is opened.
    (vi) "Other information" and "Questions" may appear outside the Drug Facts box, or inside when the package is opened, except that products containing aspartame as an inactive ingredient shall bear a statement on the outer container to the following effect: Phenylketonurics: Contains Phenylalanine (__)mg Per (Dosage Unit).
    (vii) If columns are used, the title "Drug Facts (continued)," may be omitted, provided a visual graphic (e.g., an arrow) is used to signal the continuation of the Drug Facts labeling to the next adjacent column.

(3) Alternatively, in instances where packaging constraints, such as configuration and tamper-evident features, do not permit all information to be visible on the outer package or a package insert may not be included within the package, the Drug Facts box and other information may be provided on secondary packaging, provided that the full Drug Facts labeling is provided in the form of a tear-off pad, is printed on the shelf tray used to display the product, and complies with all formatting requirements of the rule.

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Consumer Healthcare Products Association

Draft Proposed Convenience-Size Exemption for
Liquid Dosage Forms
Cough/Cold/Allergy Products

To be inserted in the Monograph:

For products packaged for easy portability and for which the printable space is insufficient to accommodate all required labeling in the required format or are single-use non-reclosable packages, or contain no more than 4 fluid ounces, the following shall apply:

(1) The 60 percent requirement stated in Sec. 201.66(d)(10) will be waived as a requirement for using the modifications given in Sec. 201.66(d)(10)(i) through Sec. 201.66(d)(10)(v).

(2) The labeling shall meet the requirements of Sec. 201.66(c) of this chapter except that
  (a) the horizontal barlines and hairlines described in Sec. 201.66(d)(8), may be omitted,.
  (b) the title, "Drug Facts" described in Sec 201.66(d)(1)and (2) is to be retained at a type size of 7.1-point, per the modified format;
  (c) headings, and information described in Sec. 201.66(c)(1), (c)(3), and (c)(7) may be omitted,
  (d) a paragraph format may be used,
  (e) the headings, subheadings, and information described in Sec. 201.66(c)(2), (c)(4), (c)(5), and (c)(6) may be presented as follows:
    (i) The active ingredients (Sec. 201.66(c)(2) of this chapter) shall be listed in alphabetical order, except the heading, "Active(s)," may be used.
    (ii) The heading and the indication required by Sec. 201.66(c)(4) may be limited to: "Use (in bold type) for [insert antihistamine, antitussive, expectorant, and/or nasal decongestant uses appropriate for the active ingredients].
    (iii) Warnings visible at the point of purchase may be limited to specialty warnings and those under the "Do not use" heading, provided that a prominent and conspicuous instruction "See inside for full Drug Facts" (or another appropriate instruction) appears on the package, and all required warnings are available when the package is opened.
    (iv) Directions may be omitted from the outside of the package, provided that a prominent and conspicuous instruction "See inside for full Drug Facts " and all required dosage instructions are available when the package is opened.
    (v) Inactive ingredients may be omitted from the outside of the package, provided a prominent and conspicuous instruction "See inside for full Drug Facts" and inactive ingredients are available when the package is opened.
    (vi) "Other information" and "Questions" may appear outside the Drug Facts box, or inside when the package is opened, except that products containing aspartame as an inactive ingredient shall bear a statement on the outer container to the following effect: Phenylketonurics: Contains Phenylalanine (__)mg Per (Dosage Unit).
    (vii) If columns are used, the title "Drug Facts (continued)," may be omitted, provided a visual graphic (e.g., an arrow) is used to signal the continuation of the Drug Facts labeling to the next adjacent column.

(3) Alternatively, in instances where packaging constraints, such as configuration and tamper-evident features, do not permit all information to be visible on the outer package or a package insert may not be included within the package, the Drug Facts box and other information may be provided on secondary packaging, provided that the full Drug Facts labeling is provided in the form of a tear-off pad, is printed on the shelf tray used to display the product, and complies with all formatting requirements of the rule.

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Consumer Healthcare Products Association

Draft Proposed Convenience-Size Exemption for
Solid Oral Dosage Forms
Cough/Cold/Allergy Products

To be inserted in the Monograph:

For products packaged for easy portability and for which the printable space is insufficient to accommodate all required labeling in the required format or are single-use non-reclosable packages, or contain no more than 12 dosage units, the following shall apply:

(1) The 60 percent requirement stated in Sec. 201.66(d)(10) will be waived as a requirement for using the modifications given in Sec. 201.66(d)(10)(i) through Sec. 201.66(d)(10)(v).

(2) The labeling shall meet the requirements of Sec. 201.66(c) of this chapter except that
  (a) the horizontal barlines and hairlines described in Sec. 201.66(d)(8), may be omitted,.
  (b) the title, "Drug Facts" described in Sec 201.66(d)(1)and (2) is to be retained at a type size of 7.1-point, per the modified format;
  (c) headings, and information described in Sec. 201.66(c)(1), (c)(3), and (c)(7) may be omitted,
  (d) a paragraph format may be used,
  (e) the headings, subheadings, and information described in Sec. 201.66(c)(2), (c)(4), (c)(5), and (c)(6) may be presented as follows:
    (i) The active ingredients (Sec. 201.66(c)(2) of this chapter) shall be listed in alphabetical order, except the heading, "Active(s)," may be used.
    (ii) The heading and the indication required by Sec. 201.66(c)(4) may be limited to: "Use (in bold type) for [insert antihistamine, antitussive, expectorant, and/or nasal decongestant uses appropriate for the active ingredients].
    (iii) Warnings visible at the point of purchase may be limited to specialty warnings and those under the "Do not use" heading, provided that a prominent and conspicuous instruction "See inside for full Drug Facts" (or another appropriate instruction) appears on the package, and all required warnings are available when the package is opened.
    (iv) Directions may be omitted from the outside of the package, provided that a prominent and conspicuous instruction "See inside for full Drug Facts " and all required dosage instructions are available when the package is opened.
    (v) Inactive ingredients may be omitted from the outside of the package, provided a prominent and conspicuous instruction "See inside for full Drug Facts" and inactive ingredients are available when the package is opened.
    (vi) "Other information" and "Questions" may appear outside the Drug Facts box, or inside when the package is opened, except that products containing aspartame as an inactive ingredient shall bear a statement on the outer container to the following effect: Phenylketonurics: Contains Phenylalanine (__)mg Per (Dosage Unit).
    (vii) If columns are used, the title "Drug Facts (continued)," may be omitted, provided a visual graphic (e.g., an arrow) is used to signal the continuation of the Drug Facts labeling to the next adjacent column.

(3) Alternatively, in instances where packaging constraints, such as configuration and tamper-evident features, do not permit all information to be visible on the outer package or a package insert may not be included within the package, the Drug Facts box and other information may be provided on secondary packaging, provided that the full Drug Facts labeling is provided in the form of a tear-off pad, is printed on the shelf tray used to display the product, and complies with all formatting requirements of the rule.

WS/WB/b 8/30/00

Consumer Healthcare Products Association

Draft Proposed Convenience-Size Exemption for
Single and Combination **Gastrointestinal Products (liquid dosage forms)**

To be inserted in the Monograph:

For products packaged for easy portability and for which the printable space is insufficient to accommodate all required labeling in the required format or are single-use non-reclosable packages or ***contain*** no more than 4 ***fluid*** ounces, the following shall apply:

(1) The 60 percent requirement stated in Sec. 201.66(d)(10) will be waived as a requirement for using the modifications given in Sec. 201.66(d)(10)(i) through Sec. 201.66(d)(10)(v).

(2) The labeling shall meet the requirements of Sec. 201.66(c) of this chapter except that
(a) the horizontal barlines and hairlines described in Sec. 201.66(d)(8), may be omitted,.
(b) the title, "Drug Facts" described in Sec 201.66(d)(1)and (2) is to be retained at a type size of 7.1-point, per the modified format;
(c) headings, and information described in Sec. 201.66(c)(1), (c)(3), and (c)(7) may be omitted,
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(e) the headings, subheadings, and information described in Sec. 201.66(c)(2), (c)(4), (c)(5), and (c)(6) may be presented as follows:
(i) The active ingredients (Sec. 201.66(c)(2) of this chapter) shall be listed in alphabetical order, ***except the heading, "Active(s)," may be used.***.
(ii) The heading and the indication required by Sec. 201.66(c)(4) may be limited to: "Use (in bold type) for sour stomach or acid indigestion" ***for antacids. [Appropriate laxative uses could be inserted in the Laxative monograph.]***
(iii) Warnings visible at the point of purchase may be limited to specialty warnings and those under the "Do not use" heading, provided that a prominent and conspicuous instruction "See ***inside for full Drug Facts"*** (or another appropriate instruction) appears on the package, and all required warnings are available when the package is opened.
(iv) Directions may be omitted from the outside of the package, provided that a prominent and conspicuous instruction "See ***inside for full Drug Facts*** " and all required dosage instructions are available when the package is opened.
(v) Inactive ingredients may be omitted from the outside of the package, provided a prominent and conspicuous instruction "See ***inside for full Drug Facts***" and inactive ingredients are available when the package is opened.
(vi) "Other information" and "Questions" may appear outside the Drug Facts box, or inside when the package is opened, except that ***products containing aspartame as an inactive ingredient shall bear a statement on the outer container to the following effect: Phenylketonurics: Contains Phenylalanine ( )mg Per (Dosage Unit).***
(vii) If columns are used, the title "Drug Facts (continued)," may be omitted, provided a visual graphic (e.g., an arrow) is used to signal the continuation of the Drug Facts labeling to the next adjacent column.

(3) Alternatively, in instances where packaging constraints, such as configuration and tamper-evident features, do not permit all information to be visible on the outer package ***or a package insert may not be included within the package***, the Drug Facts box and other information may be provided on secondary packaging, ***provided that the full Drug Facts labeling is provided in the form of a tear-off pad, is printed on*** the shelf tray used to display the product, ***and complies*** with all formatting requirements of the rule.

Consumer Healthcare Products Association

Draft Proposed Convenience-Size Exemption for Gastrointestinal Products (solid dosage forms)

To be inserted in the Monograph:

For products packaged for easy portability and for which the printable space is insufficient to accommodate all required labeling in the required format or are single-use non-reclosable packages, or ***contain*** no more than 12 dosage units, the following shall apply:

(1) The 60 percent requirement stated in Sec. 201.66(d)(10) will be waived as a requirement for using the modifications given in Sec. 201.66(d)(10)(i) through Sec. 201.66(d)(10)(v).

(2) The labeling shall meet the requirements of Sec. 201.66(c) of this chapter except that
(a) the horizontal barlines and hairlines described in Sec. 201.66(d)(8), may be omitted,.
(b) the title, "Drug Facts" described in Sec 201.66(d)(1)and (2) is to be retained at a type size of 7.1-point, per the modified format;
(c) headings, and information described in Sec. 201.66(c)(1), (c)(3), and (c)(7) may be omitted,
(d) a paragraph format may be used,
(e) the headings, subheadings, and information described in Sec. 201.66(c)(2), (c)(4), (c)(5), and (c)(6) may be presented as follows:
(i) The active ingredients (Sec. 201.66(c)(2) of this chapter) shall be listed in alphabetical order, ***except the heading, "Active(s)," may be used.***.
(ii) The heading and the indication required by Sec. 201.66(c)(4) may be limited to: "Use (in bold type) for sour stomach or acid indigestion" ***for antacids. [Appropriate laxative uses could be inserted in the Laxative monograph.]***
(iii) Warnings visible at the point of purchase may be limited to specialty warnings and those under the "Do not use" heading, provided that a prominent and conspicuous instruction "See ***inside for full Drug Facts"*** (or another appropriate instruction) appears on the package, and all required warnings are available when the package is opened.
(iv) Directions may be omitted from the outside of the package, provided that a prominent and conspicuous instruction "See ***inside for full Drug Facts*** " and all required dosage instructions are available when the package is opened.
(v) Inactive ingredients may be omitted from the outside of the package, provided a prominent and conspicuous instruction "See ***inside for full Drug Facts***" and inactive ingredients are available when the package is opened.
(vi) "Other information" and "Questions" may appear outside the Drug Facts box, or inside when the package is opened, except that ***products containing aspartame as an inactive ingredient shall bear a statement on the outer container to the following effect: Phenylketonurics: Contains Phenylalanine ( )mg Per (Dosage Unit).***
(vii) If columns are used, the title "Drug Facts (continued)," may be omitted, provided a visual graphic (e.g., an arrow) is used to signal the continuation of the Drug Facts labeling to the next adjacent column.

(3) Alternatively, in instances where packaging constraints, such as configuration and tamper-evident features, do not permit all information to be visible on the outer package ***or a package insert may not be included within the package***, the Drug Facts box and other information may be provided on secondary packaging, ***provided that the full Drug Facts labeling is provided in the form of a tear-off pad, is printed on*** the shelf tray used to display the product, ***and complies*** with all formatting requirements of the rule.

WS/WB/b 8/30/00

Consumer Healthcare Products Association

Draft Proposed Convenience-Size Exemption for Laxative Products (liquid dosage forms)

To be inserted in the Monograph:

For products packaged for easy portability and for which the printable space is insufficient to accommodate all required labeling in the required format or are single-use non-reclosable packages or contain no more than 4 fluid ounces, the following shall apply:

(1) The 60 percent requirement stated in Sec. 201.66(d)(10) will be waived as a requirement for using the modifications given in Sec. 201.66(d)(10)(i) through Sec. 201.66(d)(10)(v).

(2) The labeling shall meet the requirements of Sec. 201.66(c) of this chapter except that
  (a) the horizontal barlines and hairlines described in Sec. 201.66(d)(8), may be omitted,.
  (b) the title, "Drug Facts" described in Sec 201.66(d)(1)and (2) is to be retained at a type size of 7.1-point, per the modified format;
  (c) headings, and information described in Sec. 201.66(c)(1), (c)(3), and (c)(7) may be omitted,
  (d) a paragraph format may be used,
  (e) the headings, subheadings, and information described in Sec. 201.66(c)(2), (c)(4), (c)(5), and (c)(6) may be presented as follows:
    (i) The active ingredients (Sec. 201.66(c)(2) of this chapter) shall be listed in alphabetical order, except the heading, "Active(s)," may be used..
    (ii) The heading and the indication required by Sec. 201.66(c)(4) may be limited to: "Use (in bold type) for relief of occasional constipation."
    (iii) Warnings visible at the point of purchase may be limited to specialty warnings and those under the "Do not use" heading, provided that a prominent and conspicuous instruction "See inside for full Drug Facts" (or another appropriate instruction) appears on the package, and all required warnings are available when the package is opened.
    (iv) Directions may be omitted from the outside of the package, provided that a prominent and conspicuous instruction "See inside for full Drug Facts " and all required dosage instructions are available when the package is opened.
    (v) Inactive ingredients may be omitted from the outside of the package, provided a prominent and conspicuous instruction "See inside for full Drug Facts" and inactive ingredients are available when the package is opened.
    (vi) "Other information" and "Questions" may appear outside the Drug Facts box, or inside when the package is opened, except that products containing aspartame as an inactive ingredient shall bear a statement on the outer container to the following effect: Phenylketonurics: Contains Phenylalanine (__)mg Per (Dosage Unit).
    (vii) If columns are used, the title "Drug Facts (continued)," may be omitted, provided a visual graphic (e.g., an arrow) is used to signal the continuation of the Drug Facts labeling to the next adjacent column.

(3) Alternatively, in instances where packaging constraints, such as configuration and tamper-evident features, do not permit all information to be visible on the outer package or a package insert may not be included within the package, the Drug Facts box and other information may be provided on secondary packaging, provided that the full Drug Facts labeling is provided in the form of a tear-off pad, is printed on the shelf tray used to display the product, and complies with all formatting requirements of the rule.

WS/WB/b8/30/00

Consumer Healthcare Products Association

Draft Proposed Convenience-Size Exemption for Laxative Products (solid dosage forms)

To be inserted in the Monograph:

For products packaged for easy portability and for which the printable space is insufficient to accommodate all required labeling in the required format or are single-use non-reclosable packages, or contain no more than 12 dosage units, the following shall apply:

(1) The 60 percent requirement stated in Sec. 201.66(d)(10) will be waived as a requirement for using the modifications given in Sec. 201.66(d)(10)(i) through Sec. 201.66(d)(10)(v).

(2) The labeling shall meet the requirements of Sec. 201.66(c) of this chapter except that
  (a) the horizontal barlines and hairlines described in Sec. 201.66(d)(8), may be omitted,.
  (b) the title, "Drug Facts" described in Sec 201.66(d)(1)and (2) is to be retained at a type size of 7.1-point, per the modified format;
  (c) headings, and information described in Sec. 201.66(c)(1), (c)(3), and (c)(7) may be omitted,
  (d) a paragraph format may be used,
  (e) the headings, subheadings, and information described in Sec. 201.66(c)(2), (c)(4), (c)(5), and (c)(6) may be presented as follows:
    (i) The active ingredients (Sec. 201.66(c)(2) of this chapter) shall be listed in alphabetical order, except the heading, "Active(s)," may be used..
    (ii) The heading and the indication required by Sec. 201.66(c)(4) may be limited to: "Use (in bold type) for relief of occasional constipation."
    (iii) Warnings visible at the point of purchase may be limited to specialty warnings and those under the "Do not use" heading, provided that a prominent and conspicuous instruction "See inside for full Drug Facts" (or another appropriate instruction) appears on the package, and all required warnings are available when the package is opened.
    (iv) Directions may be omitted from the outside of the package, provided that a prominent and conspicuous instruction "See inside for full Drug Facts " and all required dosage instructions are available when the package is opened.
    (v) Inactive ingredients may be omitted from the outside of the package, provided a prominent and conspicuous instruction "See inside for full Drug Facts" and inactive ingredients are available when the package is opened.
    (vi) "Other information" and "Questions" may appear outside the Drug Facts box, or inside when the package is opened, except that products containing aspartame as an inactive ingredient shall bear a statement on the outer container to the following effect: Phenylketonurics: Contains Phenylalanine (__)mg Per (Dosage Unit).
    (vii) If columns are used, the title "Drug Facts (continued)," may be omitted, provided a visual graphic (e.g., an arrow) is used to signal the continuation of the Drug Facts labeling to the next adjacent column.

(3) Alternatively, in instances where packaging constraints, such as configuration and tamper-evident features, do not permit all information to be visible on the outer package or a package insert may not be included within the package, the Drug Facts box and other information may be provided on secondary packaging, provided that the full Drug Facts labeling is provided in the form of a tear-off pad, is printed on the shelf tray used to display the product, and complies with all formatting requirements of the rule.

WS/WB/b 8/30/00

Consumer Healthcare Products Association

Draft Proposed Convenience-Size Exemption for Topical Anorectal Products with Dosage Limitations

To be inserted in the Monograph:

For products packaged for easy portability and for which the printable space is insufficient to accommodate all required labeling in the required format or are single-use non-reclosable packages, or contain no more than 1 ounce of product, the following shall apply:

(1) The 60 percent requirement stated in Sec. 201.66(d)(10) will be waived as a requirement for using the modifications given in Sec. 201.66(d)(10)(i) through Sec. 201.66(d)(10)(v).

(2) The labeling shall meet the requirements of Sec. 201.66(c) of this chapter except that
  (a) the horizontal barlines and hairlines described in Sec. 201.66(d)(8), may be omitted,.
  (b) the title, "Drug Facts" described in Sec 201.66(d)(1)and (2) is to be retained at a type size of 7.1-point, per the modified format;
  (c) the headings, and information described in Sec. 201.66(c)(1), (c)(3), and (c)(7) may be omitted,
  (d) a paragraph format may be used,
  (e) the headings, subheadings, and information described in Sec. 201.66(c)(2), (c)(4), (c)(5), and (c)(6) may be presented as follows:
    (i) The ingredients (Sec. 201.66(c)(2) of this chapter) shall be listed in alphabetical order, except the heading, "Active(s)," may be used.
    (ii) The heading and the indication required by Sec. 201.66(c)(4) may be limited to: "Use (in bold type) (insert one or more, but not necessarily all, indications).
    (iii) Warnings visible at the point of purchase may be limited to specialty warnings and those under the "Do not use" heading, provided that a prominent and conspicuous instruction "See inside for full Drug Facts" (or another appropriate instruction) appears on the package, and all required warnings are available when the package is opened.
    (iv) Directions may be omitted from the outside of the package, provided that a prominent and conspicuous instruction "See inside for full Drug Facts " and all required dosage instructions are available when the package is opened.
    (v) Inactive ingredients may be omitted from the outside of the package, provided a prominent and conspicuous instruction "See inside for full Drug Facts" and inactive ingredients are available when the package is opened.
    (vi) "Other information" and "Questions" may appear outside the Drug Facts box, or inside when the package is opened
    (vii) If columns are used, the title "Drug Facts (continued)," may be omitted, provided a visual graphic (e.g., an arrow) is used to signal the continuation of the Drug Facts labeling to the next adjacent column.

(3) Alternatively, in instances where packaging constraints, such as configuration and tamper-evident features, do not permit all information to be visible on the outer package or a package insert may not be included within the package, the Drug Facts box and other information may be provided on secondary packaging, provided that the full Drug Facts labeling is provided in the form of a tear-off pad, or is printed on the shelf tray used to display the product, and complies with all formatting requirements of the rule.

WS/WB/b
9/26/00

Consumer Healthcare Products Association

Draft Proposed Convenience-Size Exemption for Topical Antifungal Products with Dosage Limitations

To be inserted in the Monograph:

For products packaged for easy portability and for which the printable space is insufficient to accommodate all required labeling in the required format or are single-use non-reclosable packages, or contain no more than 1 ounce of product, the following shall apply:

(1) The 60 percent requirement stated in Sec. 201.66(d)(10) will be waived as a requirement for using the modifications given in Sec. 201.66(d)(10)(i) through Sec. 201.66(d)(10)(v).

(2) The labeling shall meet the requirements of Sec. 201.66(c) of this chapter except that
   (a) the horizontal barlines and hairlines described in Sec. 201.66(d)(8), may be omitted,.
   (b) the title, "Drug Facts" described in Sec 201.66(d)(1)and (2) is to be retained at a type size of 7.1-point, per the modified format;
   (c) the headings, and information described in Sec. 201.66(c)(1), (c)(3), and (c)(7) may be omitted,
   (d) a paragraph format may be used,
   (e) the headings, subheadings, and information described in Sec. 201.66(c)(2), (c)(4), (c)(5), and (c)(6) may be presented as follows:
      (i) The ingredients (Sec. 201.66(c)(2) of this chapter) shall be listed in alphabetical order, except the heading, "Active(s)," may be used.
      (ii) The heading and the indication required by Sec. 201.66(c)(4) may be limited to: "Use (in bold type) (insert one or more, but not necessarily all, indications).
      (iii) Warnings visible at the point of purchase may be limited to specialty warnings and those under the "Do not use" heading, provided that a prominent and conspicuous instruction "See inside for full Drug Facts" (or another appropriate instruction) appears on the package, and all required warnings are available when the package is opened.
      (iv) Directions may be omitted from the outside of the package, provided that a prominent and conspicuous instruction "See inside for full Drug Facts " and all required dosage instructions are available when the package is opened.
      (v) Inactive ingredients may be omitted from the outside of the package, provided a prominent and conspicuous instruction "See inside for full Drug Facts" and inactive ingredients are available when the package is opened.
      (vi) "Other information" and "Questions" may appear outside the Drug Facts box, or inside when the package is opened
      (vii) If columns are used, the title "Drug Facts (continued)," may be omitted, provided a visual graphic (e.g., an arrow) is used to signal the continuation of the Drug Facts labeling to the next adjacent column.

(3) Alternatively, in instances where packaging constraints, such as configuration and tamper-evident features, do not permit all information to be visible on the outer package or a package insert may not be included within the package, the Drug Facts box and other information may be provided on secondary packaging, provided that the full Drug Facts labeling is provided in the form of a tear-off pad, or is printed on the shelf tray used to display the product, and complies with all formatting requirements of the rule.

WS/WB/b
9/26/00

Consumer Healthcare Products Association

Draft Proposed Convenience-Size Exemption for External Analgesic Products with Dosage Limitations

To be inserted in the Monograph:

For products packaged for easy portability and for which the printable space is insufficient to accommodate all required labeling in the required format or are single-use non-reclosable packages, or contain no more than 1 ounce of product, the following shall apply:

(1) The 60 percent requirement stated in Sec. 201.66(d)(10) will be waived as a requirement for using the modifications given in Sec. 201.66(d)(10)(i) through Sec. 201.66(d)(10)(v).

(2) The labeling shall meet the requirements of Sec. 201.66(c) of this chapter except that
  (a) the horizontal barlines and hairlines described in Sec. 201.66(d)(8), may be omitted,.
  (b) the title, "Drug Facts" described in Sec 201.66(d)(1)and (2) is to be retained at a type size of 7.1-point, per the modified format;
  (c) the headings, and information described in Sec. 201.66(c)(1), (c)(3), and (c)(7) may be omitted,
  (d) a paragraph format may be used,
  (e) the headings, subheadings, and information described in Sec. 201.66(c)(2), (c)(4), (c)(5), and (c)(6) may be presented as follows:
    (i) The ingredients (Sec. 201.66(c)(2) of this chapter) shall be listed in alphabetical order, except the heading, "Active(s)," may be used.
    (ii) The heading and the indication required by Sec. 201.66(c)(4) may be limited to: "Use (in bold type) (insert one or more, but not necessarily all, indications).
    (iii) Warnings visible at the point of purchase may be limited to specialty warnings and those under the "Do not use" heading, provided that a prominent and conspicuous instruction "See inside for full Drug Facts" (or another appropriate instruction) appears on the package, and all required warnings are available when the package is opened.
    (iv) Directions may be omitted from the outside of the package, provided that a prominent and conspicuous instruction "See inside for full Drug Facts " and all required dosage instructions are available when the package is opened.
    (v) Inactive ingredients may be omitted from the outside of the package, provided a prominent and conspicuous instruction "See inside for full Drug Facts" and inactive ingredients are available when the package is opened.
    (vi) "Other information" and "Questions" may appear outside the Drug Facts box, or inside when the package is opened
    (vii) If columns are used, the title "Drug Facts (continued)," may be omitted, provided a visual graphic (e.g., an arrow) is used to signal the continuation of the Drug Facts labeling to the next adjacent column.

(3) Alternatively, in instances where packaging constraints, such as configuration and tamper-evident features, do not permit all information to be visible on the outer package or a package insert may not be included within the package, the Drug Facts box and other information may be provided on secondary packaging, provided that the full Drug Facts labeling is provided in the form of a tear-off pad, or is printed on the shelf tray used to display the product, and complies with all formatting requirements of the rule.

WS/WB/b
9/26/00

Consumer Healthcare Products Association

Draft Proposed Convenience-Size Exemption for Topical Ophthalmic Products with Dosage Limitations

To be inserted in the Monograph:

For products packaged for easy portability and for which the printable space is insufficient to accommodate all required labeling in the required format or are single-use non-reclosable packages, or contain no more than 1 ounce of product, the following shall apply:

(1) The 60 percent requirement stated in Sec. 201.66(d)(10) will be waived as a requirement for using the modifications given in Sec. 201.66(d)(10)(i) through Sec. 201.66(d)(10)(v).

(2) The labeling shall meet the requirements of Sec. 201.66(c) of this chapter except that
  (a) the horizontal barlines and hairlines described in Sec. 201.66(d)(8), may be omitted,.
  (b) the title, "Drug Facts" described in Sec 201.66(d)(1)and (2) is to be retained at a type size of 7.1-point, per the modified format;
  (c) the headings, and information described in Sec. 201.66(c)(1), (c)(3), and (c)(7) may be omitted,
  (d) a paragraph format may be used,
  (e) the headings, subheadings, and information described in Sec. 201.66(c)(2), (c)(4), (c)(5), and (c)(6) may be presented as follows:
    (i) The ingredients (Sec. 201.66(c)(2) of this chapter) shall be listed in alphabetical order, except the heading, "Active(s)," may be used.
    (ii) The heading and the indication required by Sec. 201.66(c)(4) may be limited to: "Use (in bold type) (insert one or more, but not necessarily all, indications).
    (iii) Warnings visible at the point of purchase may be limited to specialty warnings and those under the "Do not use" heading, provided that a prominent and conspicuous instruction "See inside for full Drug Facts" (or another appropriate instruction) appears on the package, and all required warnings are available when the package is opened.
    (iv) Directions may be omitted from the outside of the package, provided that a prominent and conspicuous instruction "See inside for full Drug Facts " and all required dosage instructions are available when the package is opened.
    (v) Inactive ingredients may be omitted from the outside of the package, provided a prominent and conspicuous instruction "See inside for full Drug Facts" and inactive ingredients are available when the package is opened.
    (vi) "Other information" and "Questions" may appear outside the Drug Facts box, or inside when the package is opened
    (vii) If columns are used, the title "Drug Facts (continued)," may be omitted, provided a visual graphic (e.g., an arrow) is used to signal the continuation of the Drug Facts labeling to the next adjacent column.

(3) Alternatively, in instances where packaging constraints, such as configuration and tamper-evident features, do not permit all information to be visible on the outer package or a package insert may not be included within the package, the Drug Facts box and other information may be provided on secondary packaging, provided that the full Drug Facts labeling is provided in the form of a tear-off pad, or is printed on the shelf tray used to display the product, and complies with all formatting requirements of the rule.

WS/WB/b
9/26/00

Consumer Healthcare Products Association

Draft Proposed Convenience-Size Exemption for Topical Oral Discomfort Products with Dosage Limitations

To be inserted in the Monograph:

For products packaged for easy portability and for which the printable space is insufficient to accommodate all required labeling in the required format or are single-use non-reclosable packages, or contain no more than 1 ounce of product, the following shall apply:

(1) The 60 percent requirement stated in Sec. 201.66(d)(10) will be waived as a requirement for using the modifications given in Sec. 201.66(d)(10)(i) through Sec. 201.66(d)(10)(v).

(2) The labeling shall meet the requirements of Sec. 201.66(c) of this chapter except that
   (a) the horizontal barlines and hairlines described in Sec. 201.66(d)(8), may be omitted,.
   (b) the title, "Drug Facts" described in Sec 201.66(d)(1)and (2) is to be retained at a type size of 7.1-point, per the modified format;
   (c) the headings, and information described in Sec. 201.66(c)(1), (c)(3), and (c)(7) may be omitted,
   (d) a paragraph format may be used,
   (e) the headings, subheadings, and information described in Sec. 201.66(c)(2), (c)(4), (c)(5), and (c)(6) may be presented as follows:
      (i) The ingredients (Sec. 201.66(c)(2) of this chapter) shall be listed in alphabetical order, except the heading, "Active(s)," may be used.
      (ii) The heading and the indication required by Sec. 201.66(c)(4) may be limited to: "Use (in bold type) (insert one or more, but not necessarily all, indications).
      (iii) Warnings visible at the point of purchase may be limited to specialty warnings and those under the "Do not use" heading, provided that a prominent and conspicuous instruction "See inside for full Drug Facts" (or another appropriate instruction) appears on the package, and all required warnings are available when the package is opened.
      (iv) Directions may be omitted from the outside of the package, provided that a prominent and conspicuous instruction "See inside for full Drug Facts " and all required dosage instructions are available when the package is opened.
      (v) Inactive ingredients may be omitted from the outside of the package, provided a prominent and conspicuous instruction "See inside for full Drug Facts" and inactive ingredients are available when the package is opened.
      (vi) "Other information" and "Questions" may appear outside the Drug Facts box, or inside when the package is opened
      (vii) If columns are used, the title "Drug Facts (continued)," may be omitted, provided a visual graphic (e.g., an arrow) is used to signal the continuation of the Drug Facts labeling to the next adjacent column.

(3) Alternatively, in instances where packaging constraints, such as configuration and tamper-evident features, do not permit all information to be visible on the outer package or a package insert may not be included within the package, the Drug Facts box and other information may be provided on secondary packaging, provided that the full Drug Facts labeling is provided in the form of a tear-off pad, or is printed on the shelf tray used to display the product, and complies with all formatting requirements of the rule.

WS/WB/b
9/26/00

Consumer Healthcare Products Association

Draft Proposed Convenience-Size Exemption for Topical Antitussive Products with Dosage Limitations

To be inserted in the Monograph:

For products packaged for easy portability and for which the printable space is insufficient to accommodate all required labeling in the required format or are single-use non-reclosable packages, or contain no more than 1 ounce of product, the following shall apply:

(1) The 60 percent requirement stated in Sec. 201.66(d)(10) will be waived as a requirement for using the modifications given in Sec. 201.66(d)(10)(i) through Sec. 201.66(d)(10)(v).

(2) The labeling shall meet the requirements of Sec. 201.66(c) of this chapter except that
   (a) the horizontal barlines and hairlines described in Sec. 201.66(d)(8), may be omitted,.
   (b) the title, "Drug Facts" described in Sec 201.66(d)(1)and (2) is to be retained at a type size of 7.1-point, per the modified format;
   (c) the headings, and information described in Sec. 201.66(c)(1), (c)(3), and (c)(7) may be omitted,
   (d) a paragraph format may be used,
   (e) the headings, subheadings, and information described in Sec. 201.66(c)(2), (c)(4), (c)(5), and (c)(6) may be presented as follows:
      (i) The ingredients (Sec. 201.66(c)(2) of this chapter) shall be listed in alphabetical order, except the heading, "Active(s)," may be used.
      (ii) The heading and the indication required by Sec. 201.66(c)(4) may be limited to: "Use (in bold type) (insert one or more, but not necessarily all, indications).
      (iii) Warnings visible at the point of purchase may be limited to specialty warnings and those under the "Do not use" heading, provided that a prominent and conspicuous instruction "See inside for full Drug Facts" (or another appropriate instruction) appears on the package, and all required warnings are available when the package is opened.
      (iv) Directions may be omitted from the outside of the package, provided that a prominent and conspicuous instruction "See inside for full Drug Facts " and all required dosage instructions are available when the package is opened.
      (v) Inactive ingredients may be omitted from the outside of the package, provided a prominent and conspicuous instruction "See inside for full Drug Facts" and inactive ingredients are available when the package is opened.
      (vi) "Other information" and "Questions" may appear outside the Drug Facts box, or inside when the package is opened
      (vii) If columns are used, the title "Drug Facts (continued)," may be omitted, provided a visual graphic (e.g., an arrow) is used to signal the continuation of the Drug Facts labeling to the next adjacent column.

(3) Alternatively, in instances where packaging constraints, such as configuration and tamper-evident features, do not permit all information to be visible on the outer package or a package insert may not be included within the package, the Drug Facts box and other information may be provided on secondary packaging, provided that the full Drug Facts labeling is provided in the form of a tear-off pad, or is printed on the shelf tray used to display the product, and complies with all formatting requirements of the rule.

WS/WB/b
9/26/00

Consumer Healthcare Products Association

Draft Proposed Convenience-Size Exemption for Antitussive Lozenges

To be inserted in the Monograph:

For products packaged for easy portability and for which the printable space is insufficient to accommodate all required labeling in the required format or are single-use non-reclosable packages, or no more than 12 dosage units, the following shall apply:

(1) The 60 percent requirement stated in Sec. 201.66(d)(10) will be waived as a requirement for using the modifications given in Sec. 201.66(d)(10)(i) through Sec. 201.66(d)(10)(v).

(2) The labeling shall meet the requirements of Sec. 201.66(c) of this chapter except that
- (a) the horizontal barlines and hairlines described in Sec. 201.66(d)(8), may be omitted,.
- (b) the title, "Drug Facts" described in Sec 201.66(d)(1)and (2) is to be retained at a type size of 7.1-point, per the modified format;
- (c) headings, and information described in Sec. 201.66(c)(1), (c)(3), and (c)(7) may be omitted,
- (d) a paragraph format may be used,
- (e) the headings, subheadings, and information described in Sec. 201.66(c)(2), (c)(4), (c)(5), and (c)(6) may be presented as follows:
  - (i) The active ingredients (Sec. 201.66(c)(2) of this chapter) shall be listed in alphabetical order, except the heading, "Active(s)," may be used.
  - (ii) The heading and the indication required by Sec. 201.66(c)(4) may be limited to: "Use (in bold type) for cough."
  - (iii) Warnings visible at the point of purchase may be limited to specialty warnings and those under the "Do not use" heading, provided that a prominent and conspicuous instruction "See inside for full Drug Facts" (or another appropriate instruction) appears on the package, and all required warnings are available when the package is opened.
  - (iv) Directions may be omitted from the outside of the package, provided that a prominent and conspicuous instruction "See inside for full Drug Facts " and all required dosage instructions are available when the package is opened.
  - (v) Inactive ingredients may be omitted from the outside of the package, provided a prominent and conspicuous instruction "See inside for full Drug Facts" and inactive ingredients are available when the package is opened.
  - (vi) "Other information" and "Questions" may appear outside the Drug Facts box, or inside when the package is opened, except that products containing aspartame as an inactive ingredient shall bear a statement on the outer container to the following effect: Phenylketonurics: Contains Phenylalanine (__)mg Per (Dosage Unit).
  - (vii) If columns are used, the title "Drug Facts (continued)," may be omitted, provided a visual graphic (e.g., an arrow) is used to signal the continuation of the Drug Facts labeling to the next adjacent column.

(3) Alternatively, in instances where packaging constraints, such as configuration and tamper-evident features, do not permit all information to be visible on the outer package or a package insert may not be included within the package, the Drug Facts box and other information may be provided on secondary packaging, provided that the full Drug Facts labeling is provided in the form of a tear-off pad, is printed on the shelf tray used to display the product, and complies with all formatting requirements of the rule.

WS/WB/b
8/30/00

Consumer Healthcare Products Association

Draft Proposed Convenience-Size Exemption for Oral Anesthetic Lozenges

To be inserted in the Monograph:

For products packaged for easy portability and for which the printable space is insufficient to accommodate all required labeling in the required format or are single-use non-reclosable packages, or no more than 12 dosage units, the following shall apply:

(1) The 60 percent requirement stated in Sec. 201.66(d)(10) will be waived as a requirement for using the modifications given in Sec. 201.66(d)(10)(i) through Sec. 201.66(d)(10)(v).

(2) The labeling shall meet the requirements of Sec. 201.66(c) of this chapter except that
- (a) the horizontal barlines and hairlines described in Sec. 201.66(d)(8), may be omitted,.
- (b) the title, "Drug Facts" described in Sec 201.66(d)(1)and (2) is to be retained at a type size of 7.1-point, per the modified format;
- (c) the title, headings, and information described in Sec. 201.66(c)(1), (c)(3), and (c)(7) may be omitted,
- (d) a paragraph format may be used,
- (e) the headings, subheadings, and information described in Sec. 201.66(c)(2), (c)(4), (c)(5), and (c)(6) may be presented as follows:
  - (i) The active ingredients (Sec. 201.66(c)(2) of this chapter) shall be listed in alphabetical order, except the heading, "Active(s)," may be used.
  - (ii) The heading and the indication required by Sec. 201.66(c)(4) may be limited to: "Use (in bold type) for temporary pain of (insert "headache" or "muscular aches" or menstrual discomfort" or "toothache" or any combination of the above. [Appropriate cough/cold/allergy uses could be inserted in the cough/cold/allergy monographs.]
  - (iii) Warnings visible at the point of purchase may be limited to specialty warnings and those under the "Do not use" heading, provided that a prominent and conspicuous instruction "See inside for full Drug Facts" (or another appropriate instruction) appears on the package, and all required warnings are available when the package is opened.
  - (iv) Directions may be omitted from the outside of the package, provided that a prominent and conspicuous instruction "See inside for full Drug Facts " and all required dosage instructions are available when the package is opened.
  - (v) Inactive ingredients may be omitted from the outside of the package, provided a prominent and conspicuous instruction "See inside for full Drug Facts" and inactive ingredients are available when the package is opened.
  - (vi) "Other information" and "Questions" may appear outside the Drug Facts box or inside when the package is opened.
  - (vii) If columns are used, the title "Drug Facts (continued)," may be omitted, provided a visual graphic (e.g., an arrow) is used to signal the continuation of the Drug Facts labeling to the next adjacent column.

(3) Alternatively, in instances where packaging constraints, such as configuration and tamper-evident features, do not permit all information to be visible on the outer package or a package insert may not be included within the package, the Drug Facts box and other information may be provided on secondary packaging, provided that the full Drug Facts labeling is provided in the form of a tear-off pad, is printed on the shelf tray used to display the product, and complies with all formatting requirements of the rule.

WS/WB/b 8/30/00

Consumer Healthcare Products Association

Draft Proposed Convenience-Size Exemption for Oral Demulcent Lozenges

To be inserted in the Monograph:

For products packaged for easy portability and for which the printable space is insufficient to accommodate all required labeling in the required format or are single-use non-reclosable packages, or no more than 12 dosage units, the following shall apply:

(1) The 60 percent requirement stated in Sec. 201.66(d)(10) will be waived as a requirement for using the modifications given in Sec. 201.66(d)(10)(i) through Sec. 201.66(d)(10)(v).

(2) The labeling shall meet the requirements of Sec. 201.66(c) of this chapter except that
   (a) the horizontal barlines and hairlines described in Sec. 201.66(d)(8), may be omitted,.
   (b) the title, "Drug Facts" described in Sec 201.66(d)(1)and (2) is to be retained at a type size of 7.1-point, per the modified format;
   (c) the headings, and information described in Sec. 201.66(c)(1), (c)(3), and (c)(7) may be omitted,
   (d) a paragraph format may be used,
   (e) the headings, subheadings, and information described in Sec. 201.66(c)(2), (c)(4), (c)(5), and (c)(6) may be presented as follows:
      (i) The active ingredients (Sec. 201.66(c)(2) of this chapter) shall be listed in alphabetical order, except the heading, "Active(s)," may be used.
      (ii) The heading and the indication required by Sec. 201.66(c)(4) may be limited to: "Use (in bold type) for sore mouth or sore throat."
      (iii) Warnings visible at the point of purchase may be limited to specialty warnings and those under the "Do not use" heading, provided that a prominent and conspicuous instruction "See inside for full Drug Facts" (or another appropriate instruction) appears on the package, and all required warnings are available when the package is opened.
      (iv) Directions may be omitted from the outside of the package, provided that a prominent and conspicuous instruction "See inside for full Drug Facts " and all required dosage instructions are available when the package is opened.
      (v) Inactive ingredients may be omitted from the outside of the package, provided a prominent and conspicuous instruction "See inside for full Drug Facts" and inactive ingredients are available when the package is opened.
      (vi) "Other information" and "Questions" may appear outside the Drug Facts box or inside when the package is opened.
      (vii) If columns are used, the title "Drug Facts (continued)," may be omitted, provided a visual graphic (e.g., an arrow) is used to signal the continuation of the Drug Facts labeling to the next adjacent column.

(3) Alternatively, in instances where packaging constraints, such as configuration and tamper-evident features, do not permit all information to be visible on the outer package or a package insert may not be included within the package, the Drug Facts box and other information may be provided on secondary packaging, provided that the full Drug Facts labeling is provided in the form of a tear-off pad, is printed on the shelf tray used to display the product, and complies with all formatting requirements of the rule.

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: Oct. 18, 2000

FROM: Director
Division of OTC Drug Products, HFD-560

SUBJECT: Material for Docket No. 81N-0012

TO: Dockets Management Branch, HFA-305

[X] The attached material should be placed on public display under the above referenced Docket No.

[ ] This material should be cross-referenced to Comment No. 76N-052N

Charles J. Ganley, M.D.

Attachment